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EXAMINER	
STOKLOSA, JOSEPH A	
ART UNIT	**PAPER NUMBER**
3762	
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12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,177	STICKNEY ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 7-8, 15-19, 21, 24, 27-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kramer (US 5,405,362).

5. Kramer et al. disclose an interactive defibrillation and drug injection system that obtains and analyzes physical parameters such as an ECG signal or blood pressure (Col. 11, line 5-8), automatically determining the magnitude of which to apply a pacing stimuli, based at least in part of the physical parameters, such as the a p-wave, QRS complex, R-wave that was measured (Col. 14, line 13-23; Fig. 18F, 840), and supplying the pacing stimuli at a the determined magnitude and at a pacing rate (Col. 14, line 13-23).

6. It is noted that the limitation "automatically determining a magnitude," is satisfied by Kramer et al. in that Kramer et al. states "selectable quantities… directions from the CPU" as set forth in Col. 14, line 13-23.

7. Examiner considers the device to perform the step of analyzing, creating therapy parameters such as the stimulus magnitude, and delivery in that although Kramer discloses the system to be interactive, Kramer further discloses that these functions are performed by the "expert system" in through the use of therapy and diagnostic algorithms (e.g. Col. 11, line 35-48).

8. In the alternative it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer with eliminating system dependency on user input, in other words making the system automatic, since such a modification would provide the predictable results of providing quicker therapy by eliminating an intermediate step and providing greater patient safety by removing human error. Further it has been held that broadly providing an automatic

means to replace manual activity which has accomplished the same results involves only routine skill in the art. *In re Venner,* 120 USPQ 192.

9. With regard to claim 2, Kramer et al. disclose comparing physical parameters to predetermined parameters (800) indicative of severe bradycardia (Fig. 18F).

10. With regard to claim 3, Kramer et al. disclose comparing measured parameters to predetermined parameters indicating ventricular standstill (Col. 11, 24-34).

11. With regard to claim 7 and 8, Kramer et al. disclose determining if a shock has been delivered within a predetermined period of time (Fig. 18B, 420) as well as obtaining and analyzing updated parameters (Fig. 18B, 430).

12. With regard to claims 15-19, 21, Kramer et al. disclose delivering various non-electrotherapeutic treatments (18A, 18C). It is noted that CPR includes oxygen therapy and therefore the claim limitation of 19 is satisfied. In the alternative, it would have been obvious to one having ordinary skill in the art to modify the method taught by Kramer et al. with providing oxygen therapy, since such a modification would provide the patient with oxygen in the presence of a cardiac condition that is limiting oxygen circulation throughout the body.

13. With regards to claims 27-29, Kramer et al. disclose a controller that indicates whether further treatment is needed and determine a physical status (18A). Kramer et al. also disclose a user interface such as a keyboard or in the alternative yes or no buttons (Col. 13, lines 13-20).

14. With regard to claim 32, Kramer discloses using QRS data as well as atrial contraction or ventricular contraction to determine cardiac status and proper therapy which is indicative of at least electrical capture and mechanical capture respectively.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. in view of Kroll et al. (US 6,167,306).

17. Kramer et al. disclose the claimed invention except for detecting low cardiac output. Kroll et al. teach that it is known to detect the presence of low cardiac output (claim 39). Low cardiac output could be indicative of a block in the heart and would indicate that the patient needs stimulation in order to allow the heart to beat at a normal pace. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer et al., with detecting low cardiac output as taught by Kroll et al., since such a modification would provide the system with a method of determining if stimulation therapy is needed.

18. Claims 4-5, 8-17, 20, 23, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. in view of Snyder et al. (US 6,356,785).

19. With regard to claims 4 and 5, Kramer et al. disclose the claimed invention except for comparing the physical parameters to predetermined parameters indicating a 2nd or 3rd degree atrioventricular block. Snyder teaches comparing parameters to determine the presence of a 2nd or 3rd degree block as set forth in Col. 18, line 41-44 to provide proper treatment such as transcutaneous pacing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Kramer et al. with comparing the physical parameters to predetermined parameters indicating a 2nd or 3rd degree atrioventricular block as taught by Snyder et al. since such a modification would provide for data to base proper treatment such as transcutaneous pacing.

20. With regard to claims 8-9 and 20, 25, Kramer et al. disclose the claimed invention except for automatically adjusting the pacing stimulus based on the updated parameters. Snyder et al. teach adjusting the pacing stimulus based on the updated parameters, including blood oxygen levels, as set forth in figures 15, 16B, and 17B to provide proper therapy for the current state of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer et al. with adjusting the pacing stimulus based on the updated parameters as taught by Snyder et al. since such a modification would provide the system with adjusting the pacing stimulus based on the updated parameters for providing proper therapy for the current state of the patient.

21. With regard to claims 10 and 26, Kramer et al. disclose the claimed except terminating therapy based upon the updated physical parameters. Snyder et al. do teach terminating therapy based upon the updated physical parameters if the parameters indicate normal cardiac rhythm (see column 21, lines 36-39 and column 17, lines 10-18). Terminating the therapy once normal cardiac rhythm has been determined would be beneficial to the patient in order to prevent inducing an arrhythmia. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Kramer et al. with the early termination of therapy once normal cardiac rhythm has been detected in order to prevent inducing an arrhythmia.

22. With reference to claims 15 and 17, Kramer et al. teaches the defibrillating and pacing as described above, but does not teach determining if the heart condition would be appropriately treated with non-electrotherapeutic treatment. Snyder et al. teaches determining if the heart condition would be appropriately treated with non-electrotherapeutic treatment (see figure 4 and column 9, lines 63-67 and column 10, lines 1-6). Not all abnormal heart rhythms can be best treated by defibrillation, and therefore, attempting to treat them with defibrillation can cause damage to the heart. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Kramer et al. with the non-electrotherapeutic treatment in order to prevent causing damage to the heart.

23. With regards to claims 16 and 23, Kramer et al. teaches the defibrillating and pacing as described above, but does not teach indicating the physical status of the

patient to the user. Snyder et al. do teach indicating the physical status of the patient to the user (see column 10, lines 3-6 and column 6, lines 42-51). Alerting the user to the physical status of the user allows the user to deliver the proper therapy to the patient. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Kramer et al. with the indicating the physical status of the patient to the user so that the user can deliver the proper therapy to the patient.

24. With regards to claims 11-14, Kramer et al. in view of Snyder teach that it is known to identify and determine if pacing should be ceased based on updated parameters; however fail to teach the specific parameters including no electrical capture, no mechanical capture, failure of improvement in cardiac output, and adequate circulation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer et al. in view of Snyder et al. with the specific parameters including no electrical capture, no mechanical capture, failure of improvement in cardiac output, and adequate circulation since it was known in the art that the specific parameters including no electrical capture, no mechanical capture, failure of improvement in cardiac output, and adequate circulation is used to provide indication whether a pacing pulse would be beneficial or detrimental to the patient.

25. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. in view of Snyder et al. as applied above and further in view of Sherman et al. (US 2001/0018562).

26. Kramer et al. in view of Snyder et al. teach the claimed invention except for monitoring the patient end tidal CO_2 level. Sherman et al teach monitoring the patient's end tidal CO_2 level as set forth in page 4, paragraph 27 to provide indication of how well the heart is circulating blood. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Kramer et al. in view of Snyder et al. with monitoring the patient's end tidal CO_2 level as taught by Sherman et al., since such a modification would provide the method with an indication of how well the heart is circulating blood.

Response to Arguments

1. Applicant's arguments filed 10/7/2008 have been fully considered but they are not persuasive.

2. Applicant argues that Kramer fails to teach the system automatically determining a pacing magnitude and argues that Kramer teaches the system requiring a user to set the pacing magnitude. With regard to the cited portion of Kramer, Col. 14, lines 13-23; Kramer makes no reference to the user setting the pacing magnitude, but rather explicitly states the pacing signal to be derived from specific instructions from the CPU. Given such an explicit disclosure and lack of any reference to user input Examiner considers Kramer to sufficiently disclose the claimed limitation of "automatically determining a magnitude at which to supply pacing stimuli."

3. Applicant acknowledges that the expert system disclosed by Kramer monitors various parameters such as P waves, QRS complexes, the R wave, and atrial or ventricular contraction, and argues that Kramer does not set the pacing magnitude

based at least in part on these measured parameters. Examiner respectfully disagrees. As applicant acknowledged this at least provides the system with the ability to indicate that pacing is required. As such, the simple indication of pacing and selection of pacing therapy inherently requires some pacing magnitude, and therefore any magnitude of stimuli satisfies the limitation of determining a magnitude.

4. Applicant argues that automation of determining a pacing magnitude would not be obvious since Kramer's invention seeks to provide interaction between the system and user. Examiner respectfully disagrees. While Kramer recognizes a benefit of user interaction, Kramer also acknowledges the shortcomings of user interaction and states, "…first responders lack the training to make an independent evaluation regarding treatment of the patient with cardioversion, defibrillation, transcutaneous pacing, or drugs" (Col. 1, line 51-54). Kramer discloses that the previous drawbacks of fully automated systems is directed to legal and ethical concerns prompted by lack of human input that would hinder application and acceptance of such a system, but discloses the system would be semi-automatic in the sense that, "The expert system of the present invention receives physiological input data from measuring devices attached to the patient, analyzes the data, and issues instructions to the operator regarding patient treatment, including defibrillation, cardioversion, and drug injection" Col. 3, lines 53-58. It is clear from such disclosure that there is no user interaction in terms of determining a pacing stimulus, but rather the user interaction is only relied upon for actuating the device and delivering the therapy that has been determined by the expert system.

5. Applicant argues that Claim 7 requires the determination of whether “a defibrillation shock has been delivered within in predetermined period of time" requires that the defibrillation shock also requires determining whether a patient's heart condition is treatable through defibrillation or pacing. Claim 7 states "a defibrillation shock" therefore it is unclear if this is the same defibrillation shock set forth in claim 1 or a different shock. Further, even if claim 7 were amended to recite "the defibrillation shock” applicants arguments still fail to recognize that by the system determining to deliver a shock in the first place, block 410, the system has determined that the patients heart condition is treatable through defibrillation shock.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
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12/18/2008